



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91589d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 1, 2001

Our Reference: 2952924

Jeffrey R. Aivazian, President
The Meat Market, Inc.
454 West Alluvial Avenue
Fresno, California 93650

Dear Mr. Aivazian:

On May 15 and 16, 2001, we inspected your seafood processing facility. We conducted this inspection to determine your compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP and GMP deficiencies. The deficiencies cause your refrigerated histamine forming fish (Mahi-mahi, tuna, and Escolar) and ready-to-eat Dungeness crab to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish and crustacean have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious deficiencies are as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for Mahi-mahi and Ahi tuna does not list the food safety hazard of histamine toxin formation as a result of time/temperature abuse. Additionally, your firm processes Escolar, a histamine forming species, but it was not listed in your HACCP plan.
2. You must have a HACCP plan that list the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for ready-to-eat Dungeness crab does not list the critical control point (CCP) of Thawing for controlling the food

safety hazard of pathogen growth as a result of time/temperature abuse. Further review of your HACCP plan by the district disclosed this deficiency.

3. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor the following areas of sanitation to ensure control:

- a) Condition and cleanliness of food contact surfaces;
- b) Prevention of cross-contamination;
- c) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- d) Protection of food and food contact surfaces from adulterants;
- e) Proper labeling and storage of toxic compounds;
- f) Control of employee health conditions; and
- g) Exclusion of pests from the processing area.

Please advise us in writing, within thirty working days of receipt of this letter, the measures you have implemented to correct these violations. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your seafood firm operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley

Director

San Francisco District